

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE))
PRODUCTS LIABILITY LITIGATION) MDL NO. 1203
)
)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8897

Bartle, J.

June 19, 2012

Linda R. Burger ("Ms. Burger" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2001, claimant submitted a completed Green Form to the Trust signed by her attesting physician, George B. Bittar, M.D., F.A.C.P., F.C.C.P., F.A.C.C. Based on an echocardiogram dated September 20, 2001, Dr. Bittar attested in Part II of Ms. Burger's Green Form that, among other things, she suffered from moderate aortic regurgitation, an abnormal left atrial dimension, and an ejection fraction in the range of 50% to 60%. In May, 2003, claimant submitted a supplemental Green Form, based on a cardiac catheterization dated January 9, 2003, in which Dr. Bittar attested that, among other things, Ms. Burger suffered from moderate mitral regurgitation, severe aortic regurgitation, pulmonary hypertension secondary to severe aortic

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compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

regurgitation, an abnormal left atrial dimension, and an ejection fraction in the range of 50% to 60%. At that time, Dr. Bittar also represented that claimant had surgery to repair or replace the aortic and/or mitral valve(s). Based on such findings, claimant would be entitled to Matrix A-1,³ Level III benefits in the amount of \$675,380.⁴

Dr. Bittar also attested in each Green Form that claimant did not have aortic sclerosis. Under the Settlement Agreement, the presence of aortic sclerosis in Diet Drug Recipients who are sixty (60) years of age or older at the time they are first diagnosed as FDA Positive⁵ requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). As the Trust does not contest Ms. Burger's entitlement to Level III benefits, the only issue

3. In Part I of her May, 2003 Green Form, Ms. Burger requested Matrix Benefits at Level V. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant did not contest, that Ms. Burger only alleged conditions consistent with a claim for Level III benefits.

4. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

5. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve...." Settlement Agreement § I.22.a.

before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.⁶

In August, 2005, the Trust forwarded the claim for review by Donna R. Zwas, M.D., F.A.C.C., one of its auditing cardiologists.⁷ In audit, Dr. Zwas reviewed claimant's September 20, 2001 echocardiogram and concluded that there was no reasonable medical basis for Dr. Bittar's finding that claimant did not have aortic sclerosis. She stated, "The aortic valve leaflets are focally thickened and focally calcified, consistent with aortic sclerosis."

Based on the auditing cardiologist's finding, the Trust issued a post-audit determination that Ms. Burger was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, claimant argued that there was no evidence that her aortic

6. The Trust paid Ms. Burger Matrix B-1, Level III benefits in November, 2005.

7. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that claimant had a Matrix A-1, Level III claim, the Trust audited Ms. Burger's claim pursuant to the PPP.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Burger's claim.

sclerosis predated her Diet Drug use. Ms. Burger also contended that the damage to her heart, including the level of aortic regurgitation, was caused by her Diet Drug use. In support, claimant submitted a supplemental report from Dr. Bittar and a report from Tony K. Nasser, M.D., F.A.C.C.

The Trust then issued a final post-audit determination, again determining that Ms. Burger was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Burger's claim should be paid. On March 20, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6077 (Mar. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 9, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review a claim after the Trust

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there
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and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding with respect to aortic sclerosis. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Burger relies on a number of reports of procedures performed prior to September 20, 2001, including:

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are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

- A September 1, 1998 echocardiogram reviewed by Shantilal Patel, M.D., who reported trace aortic regurgitation;
- A February 1, 1999 echocardiogram reviewed by Dr. Patel, who reported mild aortic regurgitation;
- A February 17, 1999 cardiac catheterization performed by Dr. Patel, who did not comment on the level of Ms. Burger's aortic regurgitation; and
- An April 15, 1999 echocardiogram reviewed by Joseph E. Steinmetz, M.D., who reported mild aortic regurgitation.

In response, the Trust asserts that the results reported from these four studies "are inconclusive and contradictory, and in any event cannot be verified because the studies are no longer available." In the Final Post-Audit Determination Letter, the Trust noted that:

[Ms. Burger's] counsel has since confirmed that neither [the September 1, 1998 nor the February 1, 1999] echocardiogram still exists. Absent the echocardiograms upon which your physician relied in diagnosing you with mild aortic regurgitation prior to your 60th birthday, the Trust finds that you have failed to demonstrate, as is your burden at Contest, a reasonable medical basis for Dr. Bittar's Green Form representation that you did not have aortic sclerosis when you were first diagnosed with mild or greater aortic regurgitation if you were 60 or older at the time.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiograms performed on September 20, 2001,

January 31, 2002, and November 27, 2002, as well as claimant's cardiac catheterization performed on January 9, 2003.

Dr. Vigilante concluded that each of these studies demonstrated the presence of aortic sclerosis. Dr. Vigilante also noted that he is unable to comment regarding the presence or absence of aortic sclerosis before September 20, 2001.

In response to the Technical Advisor Report, Ms. Burger argues that Dr. Vigilante's recitation of her medical history highlights evidence proving: (1) her aortic sclerosis did not exist prior to the echocardiogram of attestation; and (2) her severe aortic insufficiency was caused by Diet Drug use and not by aortic sclerosis.

After reviewing the entire Show Cause Record, we find that Ms. Burger has demonstrated a reasonable medical basis for her claim. The presence of aortic sclerosis only reduces a claim for benefits to Matrix B-1 when it appears on the echocardiogram first diagnosing a respective claimant as FDA Positive if that claimant is 60 years of age or more. Settlement Agreement § IV.B.2.d. (2) (c)i)c); see also Green Form Appendix at 16-17. Stated differently, if a claimant is diagnosed as FDA Positive before reaching the age of 60, the absence or presence of aortic sclerosis is irrelevant. Thus, for purposes of this claim, if there is a reasonable medical basis for determining that Ms. Burger was FDA Positive before July 23, 2000 (the date she turned 60 years of age), her claim is payable on Matrix A-1,

regardless of whether her September 20, 2001 echocardiogram and later studies demonstrate aortic sclerosis.

Claimant presented the results of three echocardiograms performed prior to July 23, 2000, two of which, according to the reports, demonstrated at least mild aortic regurgitation. The Trust concluded that Ms. Burger could not sustain her burden of proving a reasonable medical basis for Dr. Bittar's Green Form representation because the echocardiograms themselves are no longer available. The Settlement Agreement, however, does not require that the actual echocardiogram tape or disk be provided in every case.

A number of provisions in the Settlement Agreement address circumstances where certain medical information, including an echocardiogram tape or disk, is no longer in existence. Specifically, the Settlement Agreement provides:

If the Class Member seeking a Matrix payment is unable to obtain the documentation described above [in Section VI.C.4.a.] through the exercise of reasonable efforts, the Trustees and/or Claims Administrator(s) shall have the right to consider other supporting documentation including but not limited to declarations of other Qualified Physician(s) under penalty of perjury setting forth opinion(s) to a reasonable degree of medical certainty to support the claim that the Class Member's condition entitles him or her to a Matrix payment, subject to review by the Court as set forth in Section VIII.D. If this evidence establishes the Class Member's condition to the satisfaction of the Trustees and/or Claims Administrator(s), the Class Member shall be entitled to receive the appropriate Matrix Compensation Benefits.

Settlement Agreement § VI.C.4.b.

Similarly, the Settlement Agreement states that:

In order to complete the submission of a Claim and qualify for Matrix Compensation Benefits under the Settlement Agreement, where a Class Member relies on a result of an Echocardiogram to establish that a Diet Drug Recipient had FDA Positive levels of regurgitation or Mild Mitral Regurgitation by the end of the Screening Period and where that Echocardiogram took place between the commencement of Diet Drug use and September 30, 1999, the Class Member must provide the Trustees and/or Claims Administrator(s) with a copy of the report of the results of the Echocardiogram and the videotape or disk of the Echocardiogram.... If the videotape or disk is no longer in existence, the Class Member must supply an affidavit under penalty of perjury from the person who last had custody of the videotape or disk stating that the videotape or disk is no longer in existence and describing the circumstances under which it came to be misplaced or destroyed.

Id. § VI.C.2.e.; see also § VI.C.2.f.

On October 18, 2010, we issued PTO No. 8549 requesting the views of Wyeth and Class Counsel on these sections of the Settlement Agreement. On November 4, 2010, Wyeth and Class Counsel submitted a joint response. According to Wyeth and Class Counsel, an affidavit as set forth in Sections VI.C.2.e. and VI.C.2.f. must be submitted "where a Class Member is unable to submit the tape or disk from an echocardiogram that the Class Member relies upon to show FDA Positive levels of regurgitation or Mild Mitral Regurgitation by the end of the Screening Period or to show Matrix-Level conditions to qualify for Matrix Compensation Benefits." (Emphasis added). The Trust will "review[] any such affidavits to determine whether the Class

Member has substantiated the necessary explanation of why the echocardiogram tape or disc cannot be furnished to the Trust for review." After that determination, Wyeth and Class Counsel stated,

[T]he Trust may rely upon other medical evidence regarding the presence or absence of the regurgitation diagnosed by the Qualifying Echocardiogram, the presence or absence of a Matrix Level condition, and the presence or absence of a Reduction Factor, including the written [echocardiogram] report of the missing tape or disk prepared when the echocardiogram was conducted and all other Medical Information submitted on the claim, such as hospital records, results of cardiac catheterizations, surgical reports, pathology reports, and any other echocardiogram studies. The Auditing Cardiologist shall weigh all such Medical Information and the totality of the medical facts presented in evaluating whether there is a reasonable medical basis for the level of regurgitation on the Qualifying Echocardiogram, the presence of a Matrix Level condition and the absence of pertinent reduction factors as asserted by the Attesting Physician in the Green Form submitted by the Class member in support of the Class Member's Matrix claim.

In the Final Post-Audit Determination Letter, the Trust explained that, "Absent the echocardiograms upon which your physician relied in diagnosing you with mild aortic regurgitation prior to your 60th birthday, the Trust finds that you have failed to demonstrate [a reasonable medical basis for your claim]."
Similarly, in the Trust's Reply, the Trust contends that the "cardiac reports" submitted by claimant are "inconclusive and contradictory." The Trust further explained:

The September 1, 1998 echocardiogram report indicates that [claimant] has trace aortic

regurgitation. The February 1, 1999 echocardiogram report indicates that [claimant] has mild aortic regurgitation. [Claimant's] February 17, 1999 report is a cardiac catheterization report and makes no mention of any aortic regurgitation. Finally, the April 15, 1999 echocardiogram report of a stress echo indicates that [claimant] has mild aortic regurgitation. Accordingly, [claimant] cannot demonstrate on a verifiable echocardiogram that she had mild or greater aortic regurgitation prior to her 60th birthday on July 23, 2000.

(Internal citations omitted).

We disagree that Ms. Burger only can meet her burden by providing the Trust with the echocardiogram tapes or disks and that the totality of the medical facts presented do not provide a reasonable medical basis for her claim. Based on the provisions of the Settlement Agreement and the views of Wyeth and Class Counsel, a claimant may rely upon other medical evidence to establish the presence or absence of a reduction factor. This other medical evidence includes, among other things, the reports of echocardiograms that are no longer in existence. Second, Ms. Burger provided the results of a number of echocardiograms performed prior to July 23, 2000. In particular, she submitted the reports of echocardiographic studies performed on September 1, 1998, February 1, 1999, and April 15, 1999. According to these reports, the echocardiograms demonstrated an increasing level of aortic regurgitation from trace to mild. Notably, different physicians interpreted the February 1, 1999 and April 15, 1999 echocardiograms as demonstrating mild aortic regurgitation. Moreover, Dr. Vigilante reviewed the available

echocardiogram tapes and concluded that Ms. Burger's September 20, 2001, January 31, 2002, and November 27, 2002 echocardiograms demonstrated moderate aortic regurgitation and that Ms. Burger's cardiac catheterization of January 9, 2003 demonstrated severe aortic regurgitation. Thus, based on the totality of the medical evidence presented, we find that there is a reasonable medical basis for the representation of Ms. Burger's attesting physician that claimant suffered from mild or greater aortic regurgitation before July 23, 2000 when she turned sixty (60) years of age because her medical records demonstrate a progression from trace to mild, and then to moderate and severe aortic regurgitation.

For the foregoing reasons, we conclude that claimant has met her burden of proving that she is entitled to Matrix A-1, Level III benefits. Therefore, we will reverse the Trust's denial of Ms. Burger's claim for Matrix A-1 benefits.